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MAY - 1 2000

David T. Read
Acting Director Regulatory Policy Staff, CDER
Food and Drug Administration
1451 Rockville Pike, HFD-7
Rockville, MD 20852

Dear Mr. Read:

The attached application for patent term extension of U.S. Patent No. 4,911,920 was filed on April 26, 2000, under 35 U.S.C. § 156.

The assistance of your Office is requested in confirming that the product identified in the application, BETAXON™ (levobetaxolol), has been subject to a regulatory review period within the meaning of 35 U.S.C. § 156(g) before its first commercial marketing or use and that the application for patent term extension was filed within the sixty-day period after the product was approved. Since a determination has not been made whether the patent in question claims a product, or the method of use of manufacturing such a product, which has been subject to the Federal Food, Drug and Cosmetic Act, this communication is NOT to be considered as notice which may be made in the future pursuant to 35 U.S.C. § 156(d)(2)(A).

Our review of the application to date indicates that the subject patent would be eligible for extension of the patent term under 35 U.S.C. § 156, unless levobetaxolol[1] has been previously approved.[2]

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[1]The chemical name of levobetaxolol hydrochloride is 2-Propanol, 1-[4-[2-(cyclopropylmethoxy)ethyl]phenoxy]-3-[(1-methylethyl)amino]-hydrochloride(S)- and its empiric formula is $C_{18}H_{29}NO_3.HCl$.

[2]It is noted that the New Drug Approvals list for February, 2000 at http://www.fda.gov/cder/da/da0200.htm shows that levobetaxolol hydrochloride is not considered a new chemical entity. The entry for NDA 02-1114, BETAXON, Active Ingredient(s): levobetaxolol hydrochloride states that the product is chemical type 2 (New derivative: A chemical derived from an active ingredient already marketed (a "parent" drug)). Betaxolol hydrochloride (racemic, includes levobetaxolol hydrochloride) was previously approved in the products Kerlone, on October 27, 1989, and Kerledex, on October 30, 1992, for example, but no record has been found of a prior approval of levobetaxolol hydrochloride alone. (See enclosure.)

Any correspondence, especially any change of address from applicant, with respect to this matter should be addressed as follows:

By mail: Commissioner for Patents
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Washington, D.C. 20231

By hand: Crystal Plaza Four, Suite 3C23
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Arlington, VA 22202

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Attn: Karin Tyson

Telephone inquiries regarding this communication should be directed to the undersigned at (703) 306-3159.

Karin Tyson, Senior Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Commissioner for Patent Examination Policy

cc: Sally S. Yeager
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Enclosure: USP Dictionary of USAN and International Drug Names (1998), Page 95
Prescription and OTC Drug Product, Patent and Exclusivity Data, Page AD22
Prescription Drug Product List, pages 3-44 and 3-45